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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,087	01/04/2007	Mei Wang	294-245 PCT/US	9089

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EXAMINER	
GITOMER, RALPH J	
ART UNIT	PAPER NUMBER
1657	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,087	WANG ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *17-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/15/10*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

The amendment received 11/15/10 has been entered and claims 1-16 are considered here. The amended title is acceptable.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/570,505. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '505 are directed to a natural product and the present claims are directed to a synthetic product. No patentable distinction is seen regarding the products because no patentability resides in the samples.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Afeyan

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Afeyan (2005/0273275) entitled "Method and System for Profiling Biological Systems" with a common inventor, no apparent assignee, and a priority date of 8/13/2001, teaches in paragraphs 4 and 5, developing drugs for diseases with multiple biomarkers and profiling with mass spec. In paragraph 6 multivariate analysis of the data is performed. See the claims.

All of the features of the claims are taught by Afeyan for the same function as claimed.

Applicant's arguments filed 11/15/10 have been fully considered but they are not persuasive.

Applicants response argues that Afeyan does not teach steps (b) to (d) of claim 1.

It is the examiner's position that Afeyan clearly (b) determines the effect of drugs of different doses on diseases, (c) prepares drugs expected to have a desired effect on a disease, and (d) determines the effect of the drug on the disease. See the flow charts in Figs. 1 and 2 of Afeyan. Performing these steps is ancient, the Ebers papyrus (circa 5565 BCE) for example is based upon these same steps.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borisy.

Borisy (2003/0096309) entitled "Screening System for Identifying Drug-Drug Interactions and Methods of Use Thereof" teaches on page 10 Example 3 and Table 1, identification of combinations of drugs to treat proliferation are is performed by analyzing the data to best determine combinations effective to inhibit lung cancer cells. In paragraph 57 various types of assay measurements are listed.

The claims differ from Borisy in that they specify the samples are tested with mass spec.

It would have been obvious to one of ordinary skill in the art at the time of the invention to test the samples of Borisy with mass spec because Borisy shows testing with cytotoxic assays, antibodies, gene assays, FRET, fluorescence microscopy, expression profiling and others. Employing mass spec for its art recognized function with the expected results would have been obvious. No novelty is seen in any of the presently claimed types of assays.

Applicant's arguments filed 11/15/10 have been fully considered but they are not persuasive.

Applicants response argues that Borisy differs from the present invention in that it uses purified components, not a multicomponent synthetic product mixture. Further, Borisy does not disclose a determination of a biological profile combined with determining a profile of the product mixture but is limited to random screening efforts.

It is the examiner's position that Borisy uses mixtures of drugs which reads on a multicomponent synthetic product mixture. And Borisy clearly correlates the drugs with their effects in various types of assays.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Huyn, Afeyan, Khwaja, Pugh.

Huyn (2002/0095260) entitled "Methods for Efficiently Mining Broad Data Sets for Biological Markers" teaches in the abstract, determining measurements from blood samples of biomarkers for assessing response to a drug. In column 1 first paragraph, various statistical methods of interpreting data is discussed.

Afeyan (2005/0283320) entitled "Method and System for Profiling Biological Systems" teaches in paragraph 8 profiling a biological system for pharmacological agent response. In paragraph 11 multivariate analysis on a plurality of data sets is shown.

Khwaja (6,379,714) entitled "Pharmaceutical Grade Botanical Drugs" teaches in column 3 last paragraph, a plant extract may contain a plurality of active ingredients which exhibit a given biological activity. An aliquot is removed, separate the aliquot into a plurality of marker fractions each of which include an ingredient and the degree of biological activity for each of the marker fractions is determined. In column 4 first paragraph the invention is useful for determining if a particular botanical material meets levels of pharmacological activity. In column 7 last paragraph, biological assay include cell proliferation assays.

Pugh (J Agricultural Food Chem) entitled "Characterization of Aloeride, A New High MW Polysaccharide from Aloe vera With Potent Immunostimulatory Activity" teaches on page 1031 isolated fractions of aloe were tested in a macrophage assay. On page 1033 Fig. 3 shows a dose response for a fraction.

The claims may differ from the above references in that they specify multivariate analysis specifically and various to separate the components of the product and various types of biological profiles.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ multivariate analysis in the methods of analysis shown by each of the above references because each reference teaches analyzing data from more than one measurement. Employing known methods to separate chemical mixtures into single compounds with the expected results would have been obvious. And the claimed biological profiles are conventional in this art.

The nature of pharmacognosy is such that most all drugs originated in natural products which are mostly a mixture of compounds and the desired activity was found in some fashion to be associated with a specific and single chemical which was then isolated or synthesized. In other cases, such as in the references above, synergy between components was investigated. The present claims read on this old method. And to vary the concentrations of components does not lend patentability, dose response curves to LD50 are conventional tools of investigation in this art.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to determining an effect of more than one synthetic drug on the profile of a disease by comparing effects of samples to controls and performing multivariate analysis. On page 13 of the specification the single example shows three unknown drugs have some unknown responses upon Alzheimer's disease, neuropathy and Parkinson's disease. This is insufficient for one of skill in this art to practice this invention as claimed.

Applicant's arguments filed 11/15/10 have been fully considered but they are not persuasive.

Applicants response argues that the Example on page 13 describes the claimed method. And a reference has been submitted by van der Greef showing a combination drug therapy is more beneficial than each of the drugs alone.

It is the examiner's position that the example is described in such general terms of how to practice the claimed method that one of skill in this art would not sufficiently understand how to perform the method. There is no doubt that multiple drugs can be more beneficial and exhibit synergism over a single drug. The van der Greef article does not mention multivariate analysis which appears to be the point of novelty and is the issue in the above rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

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